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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,885	07/30/2003	Karla Weaver	10123/00301	7939
30636 7590 01/25/2007 FAY KAPLUN & MARCIN, LLP 150 BROADWAY, SUITE 702 NEW YORK, NY 10038			EXAMINER STIGELL, THEODORE J	
			ART UNIT 3763	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/25/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/630,885

Applicant(s)

WEAVER ET AL.

Examiner

Theodore J. Stigell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 12-14, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Donowitz et al. (3,788,327). Donowitz discloses a valve apparatus comprising a first flexible disk (48) extending across a first lumen through which a flow of materials is to be controlled, the first flexible disk including a plurality of first movable elements (50,52) formed on opposite sides of at least one first slit (not numbered) extending through the first flexible disk, the first movable elements maintained in a closed position until a predetermined amount of pressure is applied to the elements, in which case the movable elements are opened to permit fluid flow. In the device of Donowitz the first movable elements are biased towards a closed position by the resilience of the material of the first flexible disk, the first slit is linear and parallel to the major axis of the first flexible disk. The device also includes biasing members (50,52) coupled to the first flexible disk substantially parallel to the first slit, the disk made of silicone, and the device being permanently sealed around the entire perimeter of lumen.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5-7, 9-11, 15-17, and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donowitz et al. (3,788,327) in view of Powers et al. (5,810,789).

Donowitz discloses a valve apparatus that includes all of the limitations as recited in claim 1. Donowitz does not disclose to add a housing attached to a dual lumen catheter with a valve apparatus in each lumen to regulate the fluid flow. Powers discloses a dual lumen catheter attached to a housing (figure 4) and a catheter with two housings, each housing having their own lumen (figure 1). Providing additional flexible members, movable elements, and biasing members is simply duplicating the valve of Donowitz. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the valve apparatus of Donowitz with the dual lumen catheter of Powers et al. to provide a catheter that can regulate flow to and from the body.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Donowitz et al. (3,788,327) in view of Ryan et al. (6,099,505). Donowitz discloses a device that includes all of the limitations as recited in claim 3, but does not disclose to include another pair of slits intersecting at the end of the first slit. Ryan et al. discloses a valve assembly with an automatic valve that includes a second pair of slits (162b, 162c) that intersect at the end of the first slit (162a). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the slits of Donowitz with the slit of Ryan et al. to make a valve that has better sealing capability.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donowitz and Powers as applied to claim 15 above, and further in view of Ryan et al. (6,099,505). Donowitz and Powers et al. disclose a device that includes all of the limitations as recited in claim 15. Hoffman and Powers et al. do not disclose to include another pair of slits intersecting at the end of the first slit. Ryan et al. discloses a valve assembly with an automatic valve that includes a second pair of slits (162b, 162c) that intersect at the end of the first slit (162a). Ryan et al. do not disclose to make the second pair of slits substantially perpendicular to the first pair of slits. However, this limitation is deemed a matter of design choice because the Applicant has not disclosed that the angle of the slits solves any stated problem or is for any particular purpose. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the slits of Donowitz and Powers with the slit of Ryan et al. to make a valve that has better sealing capability.

Response to Arguments

Applicant's arguments filed 11/06/2006 have been fully considered but they are not persuasive. In response to the Applicant's arguments that Donowitz does not disclose a "first flexible disk including a plurality of first movable elements formed on opposite sides of at least one first slit", the Examiner respectfully disagrees. The Examiner is interpreting "disk" to mean a "thin circular object" as defined by Webster's Online Dictionary. It is clear from the specification and Figure 2 that valve (48) can be considered a thin, circular object. The Applicant seems to argue that because the valve (48) is continuous with the body member (28) it cannot be considered a disk. However, this argument does not hold up when considering dependent claim 14, which recites that the disk is permanently sealed to the perimeter of the lumen. In other words, the disk is continuous with the wall surrounding the lumen. In regards to claim 8, it is the Examiner's position that Ryan does disclose a second pair of slits intersecting at the end of the first slit. The Examiner further notes that the Applicant is merely claiming a normal slit valve in the independent claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Theodore J. Stigell

